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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,842	01/11/2002	Issam Raad	UTSC:669US	7921

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EXAMINER

JASTRZAB, KRISANNE MARIE

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,842

Applicant(s)

RAAD ET AL.

Examiner

Krisanne Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 26-89 is/are pending in the application.
- 4a) Of the above claim(s) 51-68, 78 and 79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 26-50, 69-77 and 80-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 51-68 and 78-79 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The declaration filed on 5/15/2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the any of the applied references.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the applied references. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The declaration fails to support the allegations of conception with clearly dated materials supplying clear reference and evidence of the instant invention.

The declaration under 37 CFR 1.132 filed 5/15/2006 is insufficient to overcome the rejection of claims based upon Rosenberg as set forth in the last Office action because: the declaration fails to provide sufficient evidence of suprising results that would be outside of expectations of one of ordinary skill in the art in view of the recognized teachings in the art.

It is noted that the amendment incorrectly numbered the newly added claims. Claim number 87 was omitted. The claim numbering has been corrected according to Rule 126.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-5, 12, 14, 28-32, 34, 36-43, 69-71 and 80-82 are rejected under 35 U.S.C. 102(e) as being anticipated by Houze et. al. [U.S. Patent Publication No. 2004/0018241].

A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations, *Ex Parte Masham*, 2 USPQ2d 1647.

Regarding claim 1, Houze et. al. teach an antiseptic composition comprising a basic reagent (guanidines, such as alexidine and chlorhexidine; See p. 13, [0250]) and a dye (gentian violet; See p. 6, [0101]).

Regarding claim 2, Houze et. al. teach the antiseptic compound, wherein the basic reagent and the dye are bound (chlorhexidine and gentian violet, organic compounds, form a chemical bond, or covalent bond, by sharing a pair of electrons).

Regarding claim 4, Houze et. al. teach the antiseptic compound, wherein the basic reagent and the dye are linked by covalent bonding (chlorhexidine and gentian

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violet, organic compounds, form a chemical bond, or covalent bond, by sharing a pair of electrons).

Regarding claim 5, Houze et. al. teach the antiseptic composition, wherein the dye is a triarylmethane dye (gentian violet; See p. 6, [0101]).

Regarding claim 12, Houze et. al. teach the antiseptic composition, wherein the dye is gentian violet (gentian violet; See p. 6, [0101]).

Regarding claim 14, Houze et. al. teach the antiseptic composition, wherein the triarylmethane dye is gentian violet (gentian violet; See p. 6, [0101]).

Regarding claim 28, Houze et. al. teach the antiseptic composition, wherein the basic reagent is a phenoxide antiseptic (See p. 8, [0135]).

Regarding claim 29, Houze et. al. teach the antiseptic composition, wherein the phenoxide antiseptic is clofocetol (See p. 8, [0135]).

Regarding claim 30, Houze et. al. teach the antiseptic composition, wherein the phenoxide antiseptic is chloroxylonol (See p. 13, [0254]).

Regarding claim 31, Houze et. al. teach the antiseptic composition, wherein the phenoxide antiseptic is triclosan (See p. 13, [0251]).

Regarding claim 32, Houze et. al. teach the antiseptic compound, wherein the basic reagent and the dye are bound (chlorhexidine and gentian violet, organic compounds, form a chemical bond, or covalent bond, by sharing a pair of electrons).

Regarding claim 36, Houze et. al. teach the antiseptic compound, further defined by its ability to impregnate and/or coat a surface (See p. 2, [0051] – contact an area of the skin or mucous membrane).

Regarding claims 37-40, Houze et al., teach the inclusion of the composition into a polymer by impregnation. (See p. 21, paragraph 0421).

Regarding claim 41, Houze et. al. teach the antiseptic compound, wherein the surface is an organic surface (See p. 2, [0051] – contact an area of the skin or mucous membrane).

Regarding claim 42, Houze et. al. teach the antiseptic compound, wherein the surface is skin (See p. 2, [0051] – contact an area of the skin or mucous membrane).

Regarding claim 43, Houze et. al. teach the antiseptic compound, wherein the surface is a mucosal surface (See p. 2, [0051] – contact an area of the skin or mucous membrane).

Regarding claim 69, Houze et. al. teach a method for disinfecting and/or sterilizing a surface comprising applying a composition comprising a basic reagent and a dye of claim 1 to the surface (See p. 2, [0041] – contacting an area of the skin or mucous membrane, preferably the oral mucosa, with the bioadhesive composition to administer the one or more active agents).

Regarding claim 70, Houze et. al. teach the method, wherein the surface is an organic surface (See p. 2, [0041] – contacting an area of the skin or mucous membrane, preferably the oral mucosa, with the bioadhesive composition to administer the one or more active agents).

Regarding claim 71, Houze et. al. teach the method, wherein the organic surface is skin, a mucosal surface, or a wound surface (See p. 2, [0041] – contacting an area of

the skin or mucous membrane, preferably the oral mucosa, with the bioadhesive composition to administer the one or more active agents).

Claims 1, 6, 9-10, 12 and 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenberg [U.S. Patent No. 6,465,521].

Regarding claim 1, Rosenberg teaches an antiseptic composition comprising a basic reagent (chlorhexidine; See co. 1, line 48) and a dye (See col. 1, lines 38-44).

Regarding claim 6, Rosenberg teaches the antiseptic composition, wherein the dye is a monoazo dye (monoazo color; See col. 1, lines 38-44).

Regarding claim 9, Rosenberg teaches the antiseptic composition, wherein the dye is a xanthene dye (xanthene color; See col. 1, lines 38-44).

Regarding claim 10, Rosenberg teaches the antiseptic composition, wherein the dye is a anthraquinone dye (anthraquinone color; See col. 1, lines 38-44).

Regarding claim 12, Rosenberg teaches the antiseptic composition, wherein the dye is a D&C dye (D&C Yellow No. 7, D&C Yellow No. 10, etc.; See col. 1, lines 38-44).

Regarding claims 87-89, Rosenberg clearly discloses compositions with weight percentages that fall into the ratios set forth in the instant claims.

Claims 1, 8, 12-13, 74 and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Harper et. al. [U.S. Patent Publication No. 2005/0049306].

Regarding claim 1, Harper et. al. teach an antiseptic composition comprising a basic reagent (chlorhexidine; See p. 2, [0011]) and a dye (indigoid dye; See p. 11, [0148]).

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Regarding claim 8, Harper et. al. teach the antiseptic composition, wherein the dye is an indigoid dye (indigoid dye; See p. 11, [0148]).

Regarding claim 12, Harper et. al. teach the antiseptic composition, wherein the dye is an FD&C dye (FD&C Blue No. 1; See p. 11, [0148]).

Regarding claim 13, Harper et. al. teach the antiseptic composition, wherein the FD&C dye is Blue No. 1 (FD&C Blue No. 1; See p. 11, [0148]).

Regarding claim 74, Harper et. al. teach a method for disinfecting and/or sterilizing a fluid comprising adding a composition comprising a basic reagent and a dye of claim 1 into the fluid (See p. 3, [0033]).

Claims 1 and 26-27 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Parikh et. al. [U.S. Patent No. 6,123,926].

Regarding claim 1, Parikh et. al. teach an antiseptic composition comprising a basic reagent (octenidine; See col. 5, line 18-19) and a dye (coloring agents; See col. 5, lines 47-62).

Regarding claims 26-27, Parikh et. al. teach the antiseptic composition, wherein the basic reagent is a bipyridine and the bipyridine is octenidine (octenidine; See col. 5, line 18-19).

Claims 1 and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhuang et. al. [U.S. Patent Publication No. 2004/0132699].

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Regarding claim 1, Zhuang et. al. teach an antiseptic composition comprising a basic reagent (hexamidine; See p. 13, [0164]) and a dye (quinoline; See p. 13, [0168]).

Regarding claim 21, Zhuang et. al. teach the antiseptic composition, wherein the basic reagent is a guanidium compound (hexamidine; See p. 13, [0164]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper et al., as applied to claims 1, 8, 12-13, 74 and 80 above.

With respect to claims 75-77, Harper et al., clearly teaches the treatment of fluids and it would have been well within the purview of one of ordinary skill in the art to apply that treatment to any fluid in need of disinfection.

Claims 6, 7, 9, 11, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper et. al., as applied to claim 1 above, and further in view of the non-patent literature, Kirk-Othmer Encyclopedia of Chemical Technology, 3rd Ed., vol. 5, pp. 857-884.

Harper et. al. teach the antiseptic compound as described above in paragraph 6. Harper et. al. fail to teach that the dye is (1) a monoazo dye or FD&C Yellow No. 5 or 6, (2) a diazo dye or D&C Red No. 17, (3) a xanthene dye or FD&C Red No. 3, (4) a quinoline dye, (5) indigoid dye, FD&C Blue No. 2, and/or (6) the anthraquinone dye, D&C Green No. 6. The non-patent literature, Kirk-Othmer Encyclopedia of Chemical Technology provides a list of all FD&C and D&C colorants and their corresponding chemical structures. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the FD&C colors – a monoazo dye or FD&C

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Yellow No. 5 or 6, a diazo dye or D&C Red No. 17, a xanthene dye or FD&C Red No. 3, a quinoline dye, indigoid dye, FD&C Blue No. 2, and/or the anthraquinone dye, D&C Green No. 6 – into Harper et. al. because such FD&C and D&C dyes in effective amounts serve as coloring agents to produce the antimicrobial composition of the desired color, as desired in Harper et. al.

With respect to claim 20, Harper et al., clearly teach the use of quinolines and it would have been well within the purview of one of ordinary skill in the art to utilize any recognized quinoline.

Claims 3, 33 and 44-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houze et. al.

With respect to claims 2 and 33, Houze et al., teach bonded reagents and dyes and it would have been well within the purview of one of ordinary skill in the art that those bonds include ionic bonds, as dictated by the chemistry of the reagents and dyes chosen.

With respect to claim 44, Houze et. al. teach the antiseptic composition as described above, but fail to teach the impregnated and/or coated surface is a wound. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the antiseptic compound of Houze et. al. to a wound because the admixture of Houze et. al. possesses the ability to adapt for adhering to dermal or mucosal tissue (See p. 3, [0053]), where the antiseptic compound could be used to treat a wound on such an area.

With respect to claims 45-50, the composition of Houze et al., is clearly capable of application and impregnation of the surfaces claimed.

Claims 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houze et. al., as applied to claim 69 above, and further in view of Beerse et. al.

Houze et. al. teach the antiseptic composition as described above in paragraph 4, but fail to teach that the surface is an inorganic surface selected from the group comprising a floor, a table-top, a counter-top, hospital equipment, a wheel chair, gauze, and cotton. Beerse et. al. teach that antiseptic or antimicrobial compositions are highly efficacious for sterilization of hard surfaces, i.e. inorganic surfaces, such as floors, countertops, medical devices, wipes, gloves, etc. (See col. 3, line 65 to col. 4, line 14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the antiseptic composition of Houze et. al. to the inorganic surfaces, as taught by Beerse et. al., because the antiseptic composition of Houze et. al. allows for the coating of the inorganic surfaces with a protective antiseptic layer for disinfecting and cleaning such surfaces and protecting users from transmitting bacteria from surface to surface.

Claims 83-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al., in view of non-patent literature, Kirk-Othmer Encyclopedia of Chemical Technology, 3rd Ed., vol. 5, pp. 857-884.

Rosenberg et al., and Kirk-Othmer are applied as set forth above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the FD&C colors – a monoazo dye or FD&C Yellow

No. 5 or 6, a diazo dye or D&C Red No. 17, a xanthene dye or FD&C Red No. 3, a quinoline dye, indigoid dye, FD&C Blue No. 2, and/or the anthraquinone dye, D&C Green No. 6 – into Rosenberg et. al. because such FD&C and D&C dyes in effective amounts serve as coloring agents to produce the antimicrobial composition of the desired color, as desired in Rosenberg et. al.

Response to Arguments

Applicant's arguments filed 5/15/2006 have been fully considered but they are not persuasive.

Applicant argues that the references applied are not available as references based on the declarations swearing behind the references supplied in this response, however, the Examiner would disagree and maintain that those declarations fail to provide sufficient evidence to support the allegation of reduction to practice and conception of the invention prior to the dates of the applied references. Applicant fails to provide dated evidence with a clear connection to the instant invention.

Applicant further argues that the declaration showing surprising results is effective to overcome the rejection over Rosenberg, however, the Examiner would again disagree and maintain that the declaration fails to provide sufficient evidence of surprising results by verifying an excessive or unexpected result by comparison.

Election/Restrictions

This application contains claims 51-68 and 78-79 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include

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cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

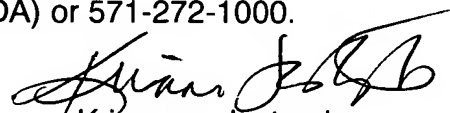
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Krisanne Jastrzab
Primary Examiner
Art Unit 1744

July 24, 2006